DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 22, 2015

Sonoma Orthopedics Products, Incorporated
% Ms. Dawn Norman
Managing Partner
Memphis Regulatory Consulting, LLC
3416 Roxee Run Cove
Bartlette, Tennessee 38133

Re: K142945
Trade/Device Name: Sonoma Fibula Repair System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: October 25, 2014
Received: October 28, 2014

Dear Ms. Norman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K142945

Device Name
Sonoma Fibula Repair System

Indications for Use *(Describe)*
The Sonoma Fibula Repair System is intended for use in the fixation of fibula fractures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Sonoma Fibula Repair System

October 9, 2014

Company: Sonoma Orthopedics Products, Inc
1388 Busch Parkway
Buffalo Grove, IL 60089
Phone: 707-526-1335
Fax: 707-526-2022

Establishment Registration: 3007038372

Primary Contact: Dawn Norman, MS
Managing Partner
Memphis Regulatory Consulting, LLC
3416 Roxee Run Cove
Bartlett, TN 38133, USA
Phone: 618-604-3064
Fax: 707-526-2022

Company/Secondary Contact:

Kyle Lappin
Sonoma Orthopedics Products, Inc
1388 Busch Parkway
Buffalo Grove, IL 60089
Phone: 707-526-1335
Fax: 707-526-2022

Trade Name: Sonoma Fibula Repair System

Common Name: Rod, Fixation, Intramedullary and Accessories

Classification: Class II

Regulation Number: 888.3020

Panel: 87- Orthopedic

Product Code: HSB

Predicate Devices: K071994 Acumed Small Bone Locking Rod System II
K031438 Acumed Small Bone Locking Rod System II

Device Description: The Sonoma Fibula Repair System includes all implants and instruments required for the fixation of fibula fractures. The Fibula Repair System includes the Sonoma Fibula Rod, Sonoma Bone Screws, End Cap and related instruments. Sonoma's Fibula Rod differs from traditional nails or rods as it utilizes Sonoma's ActivLoc® fixation gripper system at the proximal end of the rod to allow for proximal fixation without the use of screws. The implants are composed of 316 stainless steel per ASTM F138.

Indications for Use: The Sonoma Fibula Repair System is intended for use in the fixation of fibula fractures.

Substantial Equivalence: The intended use of the subject device is the same as the predicate devices. The indications for use for the subject device is limited to the fibula as opposed to additional anatomical locations for the predicate devices. The material of the subject device is the same as the Acumed Small Bone Locking Rod System (K071994). The dimensions of the subject device are within the range of the predicate devices for proximal and distal diameter, lateral bend, length, screw orientation, and placement of screws from the end of the rod. The subject device utilizes 2.7 mm diameter distal screws as opposed to 3.5 mm diameter distal screws. The subject devices use three (3) distal screws as opposed to two (2) distal screws. Thus, the subject device is substantially equivalent to the predicate devices.

Performance Testing: Engineering analysis and mechanical testing according to ASTM F1264-03(07) confirmed that the subject rods are equivalent to predicate Acumed rods in cyclic bending fatigue, static bending and static torsion.